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| 3M INNOVATIVE PROPERTIES COMPANY | | | | |
| PO BOX 33427 | | | | |
| ST. PAUL, MN 55133-3427 | | | | |
| EXAMINER | | | | |
| KOPPIKAR, VIVEK D | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 3626 | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

LegalUSDocketing@mmm.com

LegalDocketing@mmm.com

Office Action Summary

Application No.

09/729,034

Applicant(s)

PEDERSON ET AL.

Examiner

VIVEK D. KOPPIKAR

Art Unit

3626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 4/7/08.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date: _____

DETAILED ACTION

Status of the Application

1. Claims 12-37 have been examined in this application. This communication is a Final Office Action in response to the "Amendment" and "Remarks" filed on April 17, 2008.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 12-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mangram et al., 'Guideline for prevention of surgical site infection' (hereinafter Guidelines) in view of Ormond-Walshe, Sarah, "Computerized databases in infection control" (hereinafter Walshe) and in further view of US Patent Number 6,157,853 to Blume and in even further view of US Patent Number 5,562,448 to Mushabac and in even further view of US Patent Application Publication 2002/0077865 to Sullivan and in even further view of US Patent Number 6,509,730 to Afsah.

(A) As per claim 12-13, Guidelines discloses a method for managing the occurrence or risk of surgical site infection incident to a surgical procedure (Guidelines: pages 100-120), the method comprising:

(a) identifies a plurality of stages (mapping) of operative care associated with the surgical procedure, including at least a preoperative stage, an intraoperative stage, and a postoperative stage (Guidelines: page 98);

(b) identifies one or more points-of-care within each identified stage of operative

care associated with the surgical procedure (Guidelines: page 98);

(c) for each point-of-care associated with the surgical procedure, identifies one or a plurality of health care delivery practices associated with a surgical procedure sources of measurable risk of surgical site infection (Guidelines: page 98);

(d) for identified surgical site infection risks, identifying at least one practice for either or both managing or reducing the risks, either individually for each risk or collectively for more than one risk (Guidelines: pages 106-116)

Guidelines do not explicitly disclose that the identified practice or practices associated with the surgical procedure within each point-of-care to provide a set of sequential practices throughout each of the stages of operative care (pages 100-120)

Guidelines does not explicitly disclose

Aligning the practices in a manner that provides a desired management of the overall occurrence or risk of surgical site infection. However, Walshe discloses aligning the practices in a manner that provides a desired management (monitoring) of the overall occurrence or risk of surgical site infection (i.e. establishment of surveillance and control programs was strongly associated with reductions ...)(page 3). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include the aforementioned limitation as disclosed by Walshe within Guidelines for the motivation of reducing infection rates (page 3).

Guidelines and Walshe does not explicitly disclose that for each of the compliance indicators, generating a flag when a given health care practice is not in compliance with a rule to align the health care practices to the rule, however, this feature is well known in the art as

evidenced by the collective teachings of Blume (Col. 7, Ln. 16-33) in view of Mushabac (Col. 4, Ln. 56-Col. 5, Ln. 2).

Blume teaches providing real-time feedback to surgeons during a surgery but does not teach sending flags if the surgical procedure is not in compliance with a rule, however, this feature is taught by Mushabac. At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified Blume with the teachings from Mushabac with the motivation of having a means to inform a surgeon if there is a deviation (from a health care practice), as recited in Mushabac (Col. 4, Ln. 65-Col. 5, Ln. 2).

At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the teachings of Guidelines in view of Walshe with the aforementioned teachings from Blume in view of Mushabac the motivation of having a means to inform a surgeon if there is a deviation (from a health care practice), as recited in Mushabac (Col. 4, Ln. 65-Col. 5, Ln. 2).

The above mentioned references do not teach the following feature which is taught by Sullivan (Section [0055]):

wherein the health care delivery practices associated with the surgical procedure that pose a source of measurable risk or surgical site infection are selectable for a given health care facility.

At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the aforementioned references with the teachings from Sullivan with the motivation of having a means of allowing a physician to have immediate recall of difficult to remember historical items, as recited in Sullivan (Section [0055]).

The above mentioned references do not teach the following feature which is taught by Afsah (Col. 6, Ln. 9-20):

wherein at least some of the compliance indicators quantify a measure of quality associated with delivery of corresponding health care delivery practices.

At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the aforementioned references with the teachings from Afsah with the motivation of having a means of determining a benchmark value, as recited in Afsah (Col. 6, Ln. 9-11).

(B) As per claims 14-21, these claims are substantially similar in scope to claims 12-13 and are rejected on the same basis. The limitations claimed in these claims are taught in Guidelines(Pages 100-120).

(C) As per claims 22 and 36, Guidelines discloses a method for managing risks for surgical site infections incident to a surgical procedure, the method comprising:

evaluating a practice associated with the surgical procedure that poses an infection risk during a stage or the surgical procedure (Guidelines: Page 106-116);

Guidelines does not disclose storing data indicative of the practice associated with the surgical procedure as executed by one or more persons involved with the surgical procedures, however, this feature is taught by Walshe (Walshe: Page 3, Paragraph 1). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include the aforementioned limitation as disclosed by Walshe within Guidelines for the motivation of developing an enhanced means of reducing infection rates (page 3).

Guidelines in view of Walshe does not teach a step of identifying via a compliance indicator when the data indicative of the practice associated with a procedure is not in compliance with a rule established for the practice, however, this feature is well known in the art as evidenced by the collective teachings of Blume (Col. 7, Ln. 16-33) in view of Mushabac (Col. 4, Ln. 56-Col. 5, Ln. 2).

Blume teaches providing real-time feedback to surgeons during a surgery but does not teach sending flags if the surgical procedure is not in compliance with a rule and also does not teach generating a report that represents a compilation of measurement data associated with the surgical procedure, however, this feature is taught by Mushabac. At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified Blume with the teachings from Mushabac with the motivation of having a means to inform a surgeon if there is a deviation (from a health care practice), as recited in Mushabac (Col. 4, Ln. 65-Col. 5, Ln. 2).

At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the teachings of Guidelines in view of Walshe with the aforementioned teachings from Blume in view of Mushabac the motivation of having a means to inform a surgeon if there is a deviation (from a health care practice), as recited in Mushabac (Col. 4, Ln. 65-Col. 5, Ln. 2).

At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the aforementioned references with the teachings from Sullivan with the motivation of having a means of allowing a physician to have immediate recall of difficult to remember historical items, as recited in Sullivan (Section [0055]).

The above mentioned references do not teach the following feature which is taught by Afsah (Col. 6, Ln. 9-20):

wherein at least some of the compliance indicators quantify a measure of quality associated with delivery of corresponding health care delivery practices.

At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the aforementioned references with the teachings from Afsah with the motivation of having a means of determining a benchmark value, as recited in Afsah (Col. 6, Ln. 9-11).

(D) As per claim 23, in the combined method of Guidelines in view of Walshe and Jacober the step of identifying when the data indicative of the practice is not in compliance with the rule comprises generating a flag for the data (Jacoher: Claims 32 and 35). The motivation for making this modification to the method of guidelines is the same as set forth above in the rejection of claim 22.

(E) As per claims 24-25, in the combined method of Guidelines in view of Walshe and Jacober further comprises a step of prompting medical personnel to take further action when the flag is generated (Jacoher: Claims 32-35) and the flag is cleared when the further action is taken (Jacoher: Claim 34). The motivation for making this modification to the method of guidelines is the same as set forth above in the rejection of claim 22. (Note: In Jacob the medical personnel takes further action by sliding the tray of the medication dispenser to remove the medication (Claim 32)).

(F) As per claims 26-35 and 37, these claims repeat features previously addressed in the rejection of claims 12-25 and are rejected on the same basis.

Response to Arguments

5. Applicant's arguments filed on April 17, 2008 have been fully considered but they are not persuasive. The applicants' arguments will be addressed in sequential order as they were presented in the "Remarks" section on April 17, 2008.

(1) In response to applicant's argument that the prior art references of record are nonanalogous pieces of art as compared to the present application, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, all the prior art references of record relate to the problem of complying with health care delivery practices, procedures and protocols or generating alerts, flags or reports when certain practices, protocols, or procedures are not followed or complied with or indicating a quantified measure of quality. Therefore, the Office takes the position that all the prior art references of record are in fact analogous art since they attempt to address the same types of problems that the applicant's invention is attempting to address.

(2) Applicants argue that nothing in Blume, Mushabac or any of the applied references discloses or suggests computer-implemented techniques that generate a flag when a given health care delivery practice associated with the surgical procedure is not in compliance with a rule to thereby manage the risk of surgical site infection incident to the surgical procedure or techniques that identify when the data indicative of the practice associated with the surgical procedure is not in compliance with a rule established for the practice to thereby manage the risk

of surgical site infection incident to the surgical procedure. However, Blume (Col. 7, Ln. 16-33) does teach this feature when Blume talks about "real-time" feedback for a surgeon. The Office interprets this "real-time" feedback as a flag.

(3) Applicants argue that the cited portions of the Sullivan reference are not supported by its provisional application. However, the teachings of the Sullivan patent application publication which are recited in Figure 23 and Section [0055] of the patent application publication are recited on page 19 of its supporting provisional patent application (60/245,255) on page 19, from lines 13-20.

(4) Applicants request the Office to cite the portion of Afsah provisional application which supports the cited portions of the Afsah patent. To address this concern, the Office would like to point out that Figure 16 of the provisional application of the Afsah reference (60/185,129) supports the cited portion of the Afsah reference.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquire concerning this communication or earlier communications from the examiner should be directed to Vivek Koppikar, whose telephone number is (571) 272-5109. The examiner can normally be reached from Monday to Friday between 8 AM and 4:30 PM.

If any attempt to reach the examiner by telephone is unsuccessful, the examiner's supervisor, Joseph Thomas, can be reached at (571) 272-6776. The fax telephone numbers for this group are either (571) 273-8300 or (703) 872-9326 (for official communications including After Final communications labeled "Box AF").

Another resource that is available to applicants is the Patent Application Information Retrieval (PAIR). Information regarding the status of an application can be obtained from the (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAX. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, please feel free to contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sincerely,

Vivek Koppikar

8/2/2008

/C Luke Gilligan/

Supervisory Patent Examiner, Art Unit 3626

Application Number

Application/Control No.

09/729,034

Examiner

VIVEK D. KOPPIKAR

Applicant(s)/Patent under
Reexamination

PEDERSON ET AL.

Art Unit

3626